THE LANCET
Diabetes & Endocrinology

Supplementary appendix

This online publication has been corrected. The corrected version first appeared at thelancet.com on March 21, 2023.

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Ferrara A, Hedderson M M, Brown S D, et al. A telehealth lifestyle intervention to reduce excess gestational weight gain in pregnant women with overweight or obesity (GLOW): a randomised, parallel-group, controlled trial. *Lancet Diabetes Endocrinol* 2020; **8:** 490–500.

Online Supplement

Exclusion Criteria

Exclusion criteria were previously reported[1] and included multiple gestations, available measured pre-pregnancy weight only within 6 months of a prior pregnancy, diagnosed or documented medical conditions (pre-existing diabetes; current uncontrolled hypertension; thyroid disease diagnosed in last 30 days; history of cardiovascular disease, cancer, lung disease, chronic liver diseases, renal insufficiency, or serious gastrointestinal disease; history of an eating disorder or bariatric surgery; serious mental illness (i.e. recurrent major depression or suicidal ideation); current/recent history of mood or anxiety disorder; drug or alcohol use disorders; fertility-assisted pregnancy; current corticosteroid use (oral or injected); and bed rest); lack of approval from medical provider to contact patient; ≥13 weeks' gestation at time of recruitment; currently breastfeeding; gestational diabetes diagnosis or pregnancy loss before a baseline study clinic visit; and factors that may interfere with full participation in the trial, i.e., inability to communicate in English, disagreement with the pre-pregnancy weight assessed in the EHR (since GWG goal setting was based on pre-pregnancy weight assessed in the EHR), extensive travel plans during pregnancy, plans to move out of the area or to become pregnant in the next 18 months, no reliable transportation or telephone access, and disinterest in being randomized or preference for one of the two study conditions.

Diet and physical activity assessments

Within one week after both study clinic visits, 24-hour dietary recalls were conducted on three randomly selected days by trained staff at the Fred Hutchinson Cancer Research Center using the

Nutrition Data System for Research (NDSR).[2] Mean intake over the three days was used to estimate daily intake.

Physical activity was assessed for one week after both study clinic visits by an ActiGraph (ActiGraph, LLC, Pensacola, FL) wGT3X-BT accelerometer. Women were instructed to wear the accelerometer during the day and remove it at night before going to bed.[1] The Choi et al. algorithm was used to identify device wear time,[3-5] and metabolic equivalent (MET) values were estimated by an algorithm developed for wrist-worn ActiGraph devices.[4] Standard days for accelerometer wear (i.e., weekday- and weekend day-specific) were defined as the periods in which 70% of a sub-sample of participants wore the device, and a complete day was defined as a day in which the device was worn for at least 80% of a standard day.[1] The assessments included 4 to 7 complete days, including at least one weekend day;[6] all objective physical activity outcomes are presented as weighted (i.e., weekdays vs. weekend days) daily averages.

1. Brown SD, Hedderson MM, Ehrlich SF, et al. Gestational weight gain and optimal wellness (GLOW): rationale and methods for a randomized controlled trial of a lifestyle intervention among pregnant women with overweight or obesity. *BMC Pregnancy Childbirth* 2019; **19**(1): 145.
2. Sievert YA, Schakel SF, Buzzard IM. Maintenance of a nutrient database for clinical trials. *ControlClinTrials* 1989; **10**(4): 416-25.
3. Choi L, Ward SC, Schnelle JF, Buchowski MS. Assessment of wear/nonwear time classification algorithms for triaxial accelerometer. *Med Sci Sports Exerc* 2012; **44**(10): 2009-16.
4. Hibbing PR, Lamunion SR, Kaplan AS, Crouter SE. Estimating Energy Expenditure with ActiGraph GT9X Inertial Measurement Unit. *Med Sci Sports Exerc* 2018; **50**(5): 1093-102.
5. Ehrlich SF, Casteel AJ, Crouter SE, et al. Alternative Wear-time Estimation Methods Compared to Traditional Diary Logs for Wrist-Worn ActiGraph Accelerometers in Pregnant Women. *Journal for the Measurement of Physical Behaviour* 2020; **In press.**
6. Migueles JH, Cadenas-Sanchez C, Ekelund U, et al. Accelerometer Data Collection and Processing Criteria to Assess Physical Activity and Other Outcomes: A Systematic Review and Practical Considerations. *Sports Med* 2017; **47**(9): 1821-45.

Supplemental Table A. Difference in mean changes in metabolic biomarkers between intervention and usual care conditions without and with adjustment for rate of gestational weight gain between 8-15 and 29-38 weeks of gestation, and the mediating effect of rate of gestational weight gain between 8-15 and 29-38 weeks of gestation: The GLOW trial

	Between-condition difference in means (95% CI)	P value	Proportion mediated by rate of gestational weight gain between 8-15 and 29-38 weeks of gestation Percent (95% CI)	P value for mediation
Insulin, pmol/L				
Base model	-8.53 (-14.8 to -2.28)	0.01		
Base model plus adjustment for rates of gestational weight gain per week between 8-15 and 29-38 weeks of gestation	-2.74 (-9.03 to 3.55)	0.39	67.9% (16.3, 119.5)	0.01
HOMA-IR				
Base model	-0.30 (-0.53 to -0.06)	0.02		
Base model plus adjustment for rates of gestational weight gain per week between 8-15 and 29-38 weeks of gestation	-0.09 (-0.33 to 0.15)	0.47	70.2% (13.2, 127.2)	0.02
Leptin, nmol/L				
Base model	-0.51 (-0.81 to -0.22)	<0.01		
Base model plus adjustment for rates of gestational weight gain per week between 8-15 and 29-38 weeks of gestation	-0.05 (-0.32 to 0.22)	0.72	90.3% (43.7, 136.8)	<0.01

Analysis for Leptin included 173 women assigned to the intervention and 180 women assigned to usual care.
Analysis for Fasting insulin and HOMA-IR included 159 women assigned to the intervention and 171 women assigned to usual care.

GLOW Study
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Funded by National Institutes of Health

GLOW Study Protocol & Analysis Plan

SECTION 1……page 2
- **a. Final protocol**……..page 3
- **b. Summary of changes**……page 20

SECTION 2……page 28
- **c. Final statistical analysis plan**……page 29

REFERENCES……..page 31

CONFIDENTIAL

SECTION 1

CONFIDENTIAL

FINAL PROTOCOL
GLOW STUDY

INTRODUCTION

The prevalence of overweight and obesity before and during early pregnancy are increasing dramatically.[1-4] Overweight/obese women are less likely to meet the Institute of Medicine's (IOM) recommendations for gestational weight gain (GWG). This has significant health implications because excess GWG is associated with increased risk of gestational diabetes (GDM)[5,6] and having a large for gestational age (LGA) infant,[7] who is at higher risk of later obesity.

The main goal of this study is to examine the effectiveness of a randomized controlled clinical trial of diet and physical activity as compared to usual care to help overweight and obese pregnant women achieve appropriate GWG for their pre-pregnancy body mass index and weeks of pregnancy, as recommended by the IOM.[8] To achieve this goal, we will conduct a randomized lifestyle intervention program at 5 medical centers (Oakland, San Leandro, Walnut Creek, Fremont and Santa Clara) within Kaiser Permanente's Northern California Region. The trial will include 400 eligible pregnant women who have been identified with a prepregnancy BMI between 25.0 kg/m^2 and 40.0 kg/m^2 (200 women in each arm). The sample will be selected from among women with a body weight measured by a KPNC provider no more than 6 months prior to conception in their electronic medical record (EMR). Women will be enrolled by 15 weeks of pregnancy. For the intervention, we propose a pregnancy lifestyle curriculum that is delivered via 2 in-person counseling sessions and 11 telephone sessions, and up to 4 maintenance telephone sessions with study dietitians trained in motivational interviewing techniques. Participants assigned to usual care will receive standard prenatal medical care. The lifestyle intervention will be compared to usual medical care. Outcomes will be assessed through electronic medical record (EMR) data, patient surveys and study measurements assessed by trained study personnel at study clinic visits during pregnancy, and at 6 and 12-months postpartum.

Primary Outcome Measures:

1. Rate of gestational weight gain per week [Time Frame: Rate of gestational weight gain per week from prepregnancy weight to last pregnancy weight (kilograms per week)]
2. Proportion of women exceeding the Institute of Medicine's recommendation for rate of gestational weight gain per week [Time Frame: from prepregnancy weight to last pregnancy weight]

Secondary Outcome Measures:

1. Total gestational weight gain [Time Frame: from prepregnancy weight to last pregnancy weight (Total gestational weight (kilograms)]
2. Proportion of women exceeding the Institute of Medicine's recommendation for total gestational weight gain per week [Time Frame: from prepregnancy weight to last pregnancy weight]
3. Rate of gestational weight gain between study clinical assessments [Time Frame: Rate of gestational weight gain between approximately 10 weeks and 32 weeks gestation (kilograms per week)]

4. Diet [Time Frame: Change in total calories and proportion of calories from fat between study clinical assessments in pregnancy (i.e., between 10 weeks and 32 weeks gestation, approximately)]
5. Physical Activity [Time Frame: Change in physical activity between study clinical assessments in pregnancy (i.e., between 10 weeks and 32 weeks gestation, approximately]
6. Metabolic markers glycemia, insulinemia, lipids, leptin and adiponectin [Time Frame: Change in glucose, insulin, lipids, leptin and adiponectin between study clinical assessments in pregnancy (i.e., between 10 weeks and 32 weeks gestation, approximately)]

Exploratory Outcomes
The exploratory outcomes include:
1. Infant birthweight and perinatal complications
2. Cord blood metabolic markers
3. Postpartum weight retention at 6 and 12 months after delivery.
4. Children's anthropometrics at 6 and 12 months of age.

SETTING
The setting is KPNC, a large group practice prepaid health plan of 54 Medical Centers with more than 4M members who are representative of the geographic area. Women use the same Medical Center for general medicine, obstetrics and for their children's pediatric visits. This integrated system provides a unique opportunity for follow-up and retention. KPNC maintains complete clinical databases supplemented by clinical information recorded in the EMR. To meet the projected sample size, eligible women will be selected from Kaiser Permanente Oakland, Walnut Creek, Fremont, San Leandro and Santa Clara facilities.

RECRUITMENT, ELIGIBILITY & EXCLUSION CRITERIA
Identification of eligible women. All women, identified as: pregnant with a singleton; with a pre-pregnancy BMI between 25.0 and 40.0 kg/m^2; aged 18+ years; receiving medical care at the 5 selected Medical Centers; who are ≤8 weeks pregnant; have a single fetus; have a telephone; and, can give informed consent in English, will be eligible.

We have an automated program that provides real time identification of first prenatal care visits, from which we extract current weight and last menstrual period from the EMR on the same day as the first prenatal visit. Pre-pregnancy BMI is identified by searching the EMR for height and weight measurements taken by a KPNC clinical staff.

Eligible criteria. All women identified as pregnant with a singleton; with a pre-pregnancy BMI between 25.0 and 40.0 kg/m^2; aged 18+ years; receiving medical care at the 5 selected Medical Centers; and, who were identified at ≤8 weeks of gestation, are considered eligible. Eligibility and exclusion criteria are further assessed through a tiered process beginning with an EMR review to assess exclusion criteria and approval from medical providers to contact each patient.

Exclusion criteria. Any woman with: 1) multiple gestations (pregnant with more than one fetus); 2) pregnancy loss (miscarriage, abortion) before randomization; 3) fertility-assisted pregnancy; 4) pre-pregnancy diabetes; 5) uncontrolled hypertension; 6) history of miscarriage or

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stillbirth; 7) history of serious gastrointestinal diseases (like Crones) or bariatric surgery; 8) chronic hepatitis; 9) renal insufficiency; 10) thyroid disease diagnosed in the last 30 days; 11) current corticosteroid use (oral or injected); 12) history of cardiovascular disease; 13) history of lung disease such as emphysema and COPD; 14) history of cancer; 15) history of or current psychiatric conditions (serious mental health disorders including depression, post-traumatic stress disorders, bipolar disorders, etc.); 16) drug or alcohol abuse; and, 17) eating disorders; 18) more than 13 weeks of gestation at time of recruitment; 18) currently breastfeeding; 19) pre-pregnancy weight within 6 months of prior pregnancy; and, 20) a disinterest in being randomized or preference for one of the conditions will be excluded.

Additional reasons for exclusion, include: 1) a medical condition that would prevent participation in the intervention arm of the study (i.e. uncontrolled exercise induced asthma, provider recommendation to avoid exercise); and, 2) conditions that lead to diet changes (i.e., renal insufficiency).

Participants will also be excluded if they have: 1) plans to move out of the geographic area in the next two years; 2) extensive travel plans during pregnancy; 3) plans to get pregnant in the next 18 months; 4) no access to reliable transportation; 5) no access to consistent telephone; and, 6) are non-English speaking.

Provider approval. Prior to contacting patients who meet initial eligibility criteria, Kaiser Division of Research requires permission from providers to contact their patients. Thus, after assessing eligibility by reviewing the patient's EMR, we will seek authorization from the treating obstetrician before initiating participant contact. Emails will be sent to the provider of each eligible participant using a secure study-specific inbox (GLOW-study@kp.org). The email to the provider will contain:

- instructions on how to approve their patient's participation in the GLOW study;
- information about the study;
- why we would like to contact their patient;
- their patient's name and MRN; and,
- an attachment with the recruitment letter to be sent to the participant.

Providers will be asked to open the e-mail in order to approve his or her patient(s)' participation in the GLOW Study. Upon opening the email, a time-stamped return receipt will be generated, serving as a proxy for provider approval. This will alert the research assistant that the eligible participant can move to the next phase of screening.

For providers who have not opened the email, s/he will continue to be sent an email until s/he responds with either a return receipt or s/he sends an email indicating s/he does not want his or her patient contacted. If the provider does not respond, s/he will continue to receive emails until the participant is automatically removed from the provider "pending approval" list due to the patient having passed the gestational age requirements (must be less than 13 weeks gestational age).

Recruitment letter and call. We will maximize recruitment by sending brochures and letters prior to the recruitment call. After each eligible patient's medical chart has been reviewed and she has been approved for eligibility, the recruiter will contact women by telephone using an IRB-approved script. The call provides an opportunity for the participant to receive information about the study and to be screened further during an 18-question interviewer-administered

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survey. The participants will be asked questions regarding their health history, current health status and commitment level. Several of the questions overlap with exclusion criteria reviewed during the Health Connect (EMR) screen because health history may not be captured in Health Connect if the woman is new to Kaiser. In addition, participants will be asked to verify their pre-gravid weight from the electronic medical records (their last recorded pre-pregnancy weight). They will become ineligible if their self-reported weight is ± 5 pounds of what was recorded in their electronic medical record. We require this agreement to facilitate negotiation between lifestyle coaches and participants assigned to the intervention condition in setting the total amount of weight to be gained during pregnancy.

Orientation session. If a potential participant has been successfully screened for eligibility during the recruitment call, she will be scheduled to attend a phone-based 40-minute GLOW orientation. Orientation sessions will be conducted using motivational interviewing techniques, and will provide an opportunity to clarify trial requirements, resolve ambivalence about participating, and to build participants' commitment to the scientific premise of the study. The GLOW Orientation session will be remotely delivered to support broad dissemination and to increase the rate of participation. The material will be presented by one of the study researchers (Research Scientists or Program Manager) and will last no longer than 40 minutes.

Once the participant has been scheduled for the orientation, she will be sent an orientation reminder letter or email, which includes the orientation presentation. If emailed prior to the orientation, the participant will be asked to download the attached orientation presentation. The reminder letter will direct the participant to call the GLOW Study conference line. After the orientation, if the participant decides to join the study, research staff will make a follow-up call to schedule her baseline clinic visit appointment.

Baseline clinic visit exclusion criteria.

Women who complete the baseline clinic visit, which includes the collection of anthropometric and survey data, will be asked to complete a diet and physical activity assessment within two weeks of the visit. They will be asked to complete three 24-hour diet recalls (by telephone) and to wear an accelerometer for 10-hours for at least 4 days in addition to recording their on- and off-wear times and engagement in special activities (yoga, swimming, jogging with a stroller) in a written log. Completion of these assessments will serve to assess participants' level of commitment to the study in addition to providing baseline data on diet and physical activity. If participants complete less than four 10-hour days of accelerometer data and fewer than two diet recalls they will not be considered eligible for randomization.

RANDOMIZATION

Eligible women who consent and complete the baseline clinic visit, including the diet recall and physical activity assessments, will be considered ready for randomization. The project manager will be informed of key variables collected by study staff at the recruitment call (i.e., self-reported race/ethnicity), age and BMI (calculated using EMR weight and height taken at the baseline clinic assessment). The project manager will then invoke a randomization program called MinimPy—a free open-source computer program, to generate the patient's group assignment[9] to the intervention or control arms. This is will ensure that equal numbers of patients are assigned to each study arm and that the two arms remain balanced within each Medical Center, overall, and on each level of key characteristics: age (<30 and >=30), pre-gravid BMI (25.0-29.9, 30.0-34.9, and 35.0-40.0 kg/m^2), and race-ethnicity (White; Black; Asian/Pacific Islander;

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Hispanic; and multiracial/other). The process cannot be manipulated by site personnel. The final assignment will be recorded in the ACCESS-based tracking system, which is only accessible to non-blinded study personnel (i.e., not to data collectors). Women will be informed of their randomization assignment by lifestyle coaches via telephone and mail.

RETENTION

Strategies to maximize retention and follow up, and Incentives. We will maximize retention by sending pregnancy and postpartum newsletters, congratulatory postcards after delivery, non-denominational holiday cards, delivery measurement reminder cards and a congratulatory magnet. We will also offer $50 Target gift certificates for the completion of each clinic assessment (for a total of $250 in Target gift cards). Staff will help schedule study visits in conjunction with obstetric and pediatric visits. Women who leave KP can continue to participate in the study. In addition, participants will be asked at the end of each survey whether their contact information has changed or whether a friend or family member can be contacted in the event they are unreachable for scheduling their next visit.

TRACKING SYSTEM

Contact information and key characteristics used for randomization will be entered into a secure ACCESS database. The database will document each woman's participation status, track data collection, and intervention contacts achieved and provide a means for the regular monitoring and reporting of trial progress.

USUAL MEDICAL CARE

In addition to the standard KPNC pregnancy care, women in the usual care arm will receive 4 newsletters focused on women's health, infant safety and safety during pregnancy. Newsletters will not address diet, physical activity or gestational weight gain but will encourage participation in the study and follow-up visits.

LIFESTYLE INTERVENTION

In addition to the standard care, women assigned to the intervention will receive a multi-component pregnancy lifestyle intervention called "Getting in Balance." The Getting in Balance intervention was adapted from the DPP [10] and our prior research [11,12] to be feasible among pregnant women for possible adoption in a healthcare system setting. The intervention targets behavior changes for weight management, healthy eating, physical activity, and stress management to meet a trial goal of gaining at the lower limit of the IOM-recommended range for GWG: 7 kg for women with overweight (BMI 25.0-29.9 kg/m^2) and 5 kg for women with obesity (BMI ≥ 30.0 kg/m^2).

INTERVENTI STRUCTURE AND CONTENT.

The intervention includes an **Early Prenatal (Phase I)**, and a **Late Prenatal (Phase II)** component.

Early Prenatal (Phase I) starts soon after randomization**.**

Intervention structure and content. The intervention will be delivered by trained lifestyle coaches through 13 individual weekly counseling sessions: a first in-person session (60 minutes in duration), followed by 11 telephone sessions (20 minutes each) and a final in-person session (60 minutes; Table 1). Coaches will be registered dietitians trained in physical activity, weight management during pregnancy, motivational interviewing, and behavior change techniques.

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Coaches will receive regular group and individual supervision from master's- and doctoral-level study staff.

The session content will be supplemented with a 13-chapter workbook (Getting in Balance workbook) that aligns with the structure of the in-person and telephone sessions. The individual telephone counseling calls are designed to provide an opportunity for discussion of the written materials (available in the Getting in Balance workbook). The goals of the program are to help women in four major areas: *1) managing weight; 2) improving nutrition; 3) increasing/ maintaining physical activity; and, 4) managing stress.*

Individual In-Person and Telephone Sessions. An intervention covering diet, physical activity, weight management, stress management and continuing motivation for behavior change will be delivered via *13 brief, weekly, individually tailored counseling sessions*: 2 in-person and 11 telephone contacts, ~60 and ~20 minutes long, respectively. We will leverage the intervention used in DEBI and GEM, which was similar to the DPP intervention,[13] but adapted for pregnant and postpartum women and delivered by telephone. The first and last sessions will be delivered in-person at women's obstetric clinics.

At the first in-person session, women will be taught their risk of developing pregnancy complications, possible risk reduction via a healthy lifestyle and gestational weight gain (GWG) management, and the beneficial effects of GWG management to reduce postpartum weight retention. Individualized diet, physical activity, and GWG goals will be tailored based on stage of change, pre-pregnancy BMI, and amount of weight already gained during pregnancy. Dieticians will discuss rate of GWG per week to reach total GWG goals.

Women will receive study materials and tools, including: 1) personalized graphs of GWG trajectories; 2) a workbook of the 13-session curriculum (see Table 1); 3) the option of tracking their diet (calorie and fat intake), physical activity, and weight using: a fat counter and 12 "Keeping Track" booklets with self-addressed stamped envelopes to mail booklets in weekly; or using a study-specific Nutrihand diet and physical activity tracking website; or using a diet and physical activity smartphone tracking application like MyFitnessPal; and, 4) a study-issued *Eat Smart Precision Plus* bathroom scale to measure their weight daily. All in-person and telephone sessions will provide regular, credible, individualized counseling[14] regarding progress towards short-term diet, physical activity, stress management and GWG goals. Dieticians will collaboratively address barriers and solutions to meeting goals, motivation, and relapse prevention.

Women will achieve gestational weight gain (GWG) goals through healthy diet and regular, moderate intensity physical activity. The 2009 Institute of Medicine's (IOM) guidelines[8] for total GWG vary according to pre-pregnancy BMI: 7.0-11.5 kg for overweight women (BMI 25.0-29.9 kg/m^2) and 5-9 kg for obese women (BMI ≥30.0 kg/m^2). We chose to recommend the lower bound value set by the IOM for total GWG as the upper limit for weight gain during pregnancy: 4.9 kg (15 lbs.) for overweight women and 6.8 kg (11 lbs.) for obese women. Women will be advised on how much weight to gain per week, on average, based on their electronic medical record pre-pregnancy BMI, weight measured within 6 months of conception (value taken from

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the EMR and confirmed within 5 pounds on the recruitment call), their most recent estimated delivery date, amount of weight already gained, and weeks of pregnancy. Weight gain progress and personalized feedback will be discussed in each counseling session. Many participants may begin the trial above the goal weight for their gestational age (e.g., having gained 15 pounds within the first trimester). Thus, we anticipate recommending that many women maintain their weight for a period of time during the second trimester of their pregnancy.

Table 1. Overview of core sessions for the *Getting in Balance* intervention

Session title	**Topic**
1. Welcome to *Getting in Balance*	▪ Introduction to program goals ▪ Demonstration and instruction on how to self-monitor weight and dietary intake
2. Getting Started with Healthy Eating	▪ Diet quality; portion sizes ▪ General guidance on goal setting ▪ Set initial calorie goal
3. Getting Started with Physical Activity	▪ Safety and benefits of physical activity during pregnancy
4. Track Down Fat	▪ Types of dietary fat ▪ Moderating total fat and saturated/trans fat intake
5. Manage Stress	▪ Sources of stress ▪ Coping and relaxation skills
6. Exercise Your Options	▪ Maintaining and increasing physical activity ▪ Physical activity intensity during pregnancy
7. Celebrate Your Success	▪ Highlighting progress made to date ▪ Dietary strategies for weight management
8. Healthy Eating Out	▪ Behavioral and dietary strategies for eating well at restaurants
9. Handle Challenging Feelings and Triggers	▪ Problem solving challenging situations ▪ Prompts and cues; stimulus control
10. Staying on Track During Social Activities	▪ Social support ▪ Behavioral strategies for eating in social settings
11. Turn Setbacks into Success	▪ Relapse prevention
12. Talk Back to Negative Thoughts	▪ Cognitive distortions ▪ Cognitive reframing
13. Stay Motivated	▪ Highlighting progress made to date ▪ Planning for continued progress in last trimester

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Physical activity. In accordance with ACOG[15] recommendations, women will be advised to engage in 30-50 minutes of moderately intense physical activity (e.g., brisk walking) 5 or 3 days per week, with the goal of gradually attaining a total of 150 minutes per week. Physical activity recommendations will be tailored to each woman's health status, preferences, and need to minimize injury and maximize the convenience, safety, and enjoyment of physical activity.

Diet. The emphasis will be on overall "healthy eating" versus a restrictive "diet," i.e., eating more healthy vegetables, fruits, lean protein and high fiber foods while reducing fat and added sugars. The use of monounstaturated fats and complex carbohydrates will be recommended. Coaches will also promote awareness of portion sizes and choosing healthier options in support of lowering overall energy intake. The diet will be tailored to women's needs, access to healthy foods, and cultural preferences.

To help manage gestational weight gain, women will be given a personalized calorie goal. At each session and in consultation with the intervention team, coaches will evaluate women's weight gain trajectories in relationship to their calorie goals. The initial goal for calorie intake will be based on the participant's overall weight gain progress, weight gain between sessions 1 and 2, and on the previous week's food and calorie tracking information. The initial calorie goal will be determined by interventionists, using the *Session 2: Initial Calorie Goal Setting* schema outlined below.

At Sessions 3-17, interventionists will review participants' individual weight gain progress and make calorie goal adjustments based on between-session weight-gain and the previous week's calorie goal. Subsequent calorie goals will be determined by interventionists, using the *Sessions 3-17: Calorie Goal Adjustments* schema outlined on the next page.

Session 2: Initial Calorie Goal Setting	
Scenario…	***Interventionist instructions…***
If the participant HAS tracked her diet for more than one day or more in the last week (7 days), and HAS NOT exceeded 0.5 lbs weight gain…	provide a calorie goal based on last week's calorie information (continue what she has been doing).
If the participant HAS tracked her diet for more than one day or more in the last week (7 days), and HAS exceeded 0.5 lbs weight gain…	recommend a 200 calorie decrease for the following week; however, don't recommend a calorie goal below 1200 calories.
If the participant HAS NOT tracked her diet in the last week and HAS NOT exceeded 0.5 lbs weight gain…	the calorie goal should be established through the *GIB 24-hour Diet Recall Procedure*. The re-established calorie goal is based on the total calories calculated from the diet recall.
If the participant HAS NOT tracked her diet in the last week and HAS exceeded 0.5 lbs weight gain…	the calorie goal should be reestablished through the *GIB 24-hour Diet Recall Procedure.* The re-established calorie goal is based on the total calories calculated from the diet recall minus 200 calories; however, adjustments will be made if reducing calories by 200 results in the new calorie goal being below 1200 calories per day. (note: the calorie goal should not be below 1200)

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Sessions 3-17: Calorie Goal Adjustments	
Scenario…	***Interventionist instructions…***
If the participant HAS tracked her diet for one day or more in the last week (7 days), is meeting her calorie goal and HAS NOT exceeded 0.5 lbs weight gain…	provide a calorie goal based on last week's calorie information (continue what she has been doing).
If the participant HAS tracked her diet for one day or more in the last week (7 days), is meeting her calorie goal and HAS exceeded 0.5 lbs weight gain…	recommend a 200 calorie decrease for the following week; however, don't recommend a calorie goal below 1200 calories.
If the participant HAS tracked her diet for one day or more in the last week (7 days), is exceeding her calorie goal and HAS exceeded 0.5 lbs weight gain…	don't adjust the calorie goal. Instead, utilize motivational interviewing techniques to strategize on how to meet the currently set calorie goal.
If the participant HAS tracked her diet for one day or more in the last week (7 days), is exceeding her calorie goal and HAS NOT exceeded 0.5 lbs weight gain…	don't adjust the calorie goal. Instead, re-evaluate weight gain at the subsequent session.
If the participant HAS NOT tracked her diet in the last week and HAS NOT exceeded 0.5 lbs weight gain…	the calorie goal should be established through the *GIB 24-hour Diet Recall Procedure*. The re-established calorie goal is based on the total calories calculated from the diet recall.
If the participant HAS NOT tracked her diet in the last week and HAS exceeded 0.5 lbs weight gain…	the calorie goal should be reestablished through the *GIB 24-hour Diet Recall Procedure.* The re-established calorie goal is based on the total calories calculated from the diet recall minus 200 calories; however, adjustments will be made if reducing calories by 200 results in the new calorie goal being below 1200 calories per day. (note: the calorie goal should not be below 1200)

For example, coaches will recommend an initial calorie goal that is equivalent to current intake for participants whose weight is at or below the target weight for their gestational age; otherwise, coaches will recommend a 200-calorie reduction. At each subsequent session, coaches will engage participants in systematic problem solving to generate effective strategies to meet the calorie goal [16,17]; and collaborate with participants to adjust the goal as needed given their weight gain trajectory. For example, coaches will recommend retaining the same calorie goal for participants who are meeting the calorie goal, are near the target weight for their gestational age, and have gained no more than 0.5 lbs. in the prior week. In contrast, coaches will recommend decreasing the goal by 200 calories for participants who are meeting the goal but have gained 0.5 lbs. or more in the past 1-2 weeks. Recommended calorie goals will never be fewer than 1200 calories at any point during the intervention. Throughout the intervention, participants will be encouraged to self-monitor their weight daily using the study-provided scale, with an emphasis on attending to patterns of weight change over time (e.g., over 1- to 2-week periods, rather than any single day's measurement); and to self-monitor their dietary intake and physical activity daily using paper-based logs or commercially-available web- or mobile-based apps (e.g., MyFitnessPal).

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Late Prenatal (Phase II, maintenance).
Duration. Phase II will begin when women complete all 13 core sessions and will end at 38 weeks of gestations.
Content. It will help women internalize diet and physical activity patterns and skills established in Phase I (e.g., self-regulatory skills; active problem-solving to maintain behavior changes).
Telephone Sessions. Four 15-minute, bi-weekly phone-based sessions with the lifestyle coach will be scheduled to assist participants in continuing to monitor their weight towards the end of their pregnancy. The interventionist and the participant will use the *Use Options Tool from the Guidebook* to collaboratively decide on which topics from the 13-core session to repeat.
Target. To promote a successful transition to self-maintenance of positive behavioral changes.

Training
Interventionists. Interventionists will be study dietitians housed at the KPNC Perinatal Center. All dieticians will receive 16-hours of standardized training in social cognitive strategy and MI for diet and physical activity behavior change and will attend 1 half-day training session per year. In addition, interventionists will be provided with a 6-week training covering areas, including overview of the GLOW study, overview of the Getting in Balance Program, interviewing techniques, compliance and handling of private health information, team communication, clinic etiquette and general clinic safety, ACCESS database tracking system, data entry and scheduling. Intervention-specific trainings will cover protocols related to each program goal (weight, improving nutrition, increasing physical activity and managing stress), conducting sessions (sequence and content, scheduling, session reminders and call attempts), key principles underlying the intervention, retention, quality assurance, intervention fidelity and intervention evaluation. We will emphasize culturally sensitive delivery and tailored recommendations to meet the needs of the diverse women.

Adherence to the Intervention Protocol and Monitoring of the Intervention Process.
Our systematic approach to intervention fidelity follows a framework of five key components: trial design, training, and intervention delivery, receipt, and enactment.[18]

Trial design includes intervention "dose," i.e., the standardized number, length, duration, and format of sessions.

Training (see also above) will be standardized by simultaneously training all interventionists in group settings; recruiting staff with equivalent credentials; and using a treatment manual, case illustrations, and role play. Interventionists will be study dietitians housed at the KPNC Perinatal Center. All dieticians will receive 16 hours of standardized training in skill building, role playing, cognitive strategy and motivational interviewing for reducing barriers and enhancing awareness of the benefits of a healthy diet and exercise, prior to initiating the intervention. Training in culturally sensitive delivery and tailored exercise and diet recommendations will be emphasized to meet the needs of the diverse women in this study. Upon completion of the training session, coaches will receive a certification and be evaluated 6-months post-training.

Intervention delivery will be standardized through interventionists' written manuals/scripts and participants' written materials. Interventionists' adherence to treatment delivery, including motivational interviewing techniques, will be assessed qualitatively and quantitatively through weekly group and individual supervision, and a systematic review and coding of audiotaped sessions using fidelity checklists. After receiving patient permission, interventionists will digitally record all sessions. The dietitians will use digital recording devices and be required to record, after receiving

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patient permission, all of their telephone calls. The digital recorder creates electronic audio files that can be saved on a computer and later be selected for review by the project coordinator and/or investigators; thus, the coaches will not know which of their sessions will be reviewed for quality control purposes. The project manager will review a random 20% sample 5-sessions representative of the program goals and key intervention components across the core 13-session curriculum:

- Session 1: Welcome to Getting in Balance
- Session 2: Getting Started with Healthy Eating
- Session 3: Getting Started with Physical Activity
- Session 9: Handle Challenging Feelings and Triggers
- Session 13: Staying Motivated

Adherence will be qualitatively assessed as well as quantified using a checklist of process and content variables, including MI techniques. Interventionists will document process measures (e.g., session length) in an electronic tracking system, allowing delivery to be monitored with automated queries. Feedback will be provided weekly, allowing protocol deviations, "difficult" contacts, and MI skills to be addressed quickly. Non-specific treatment effects, i.e., interventionist characteristics such as perceived supportiveness that could impact outcomes, will be assessed by surveying participants following the Early Prenatal Phase I.

Intervention receipt, i.e., participants' engagement and comprehension of intervention concepts, will be enhanced by the interactive nature of each session. Interventionists will document session attendance in the study tracking system.

Intervention enactment, i.e., performance of skills in daily life, will be assessed during each session through verbal self-report and completion of self-monitoring records. Interventionists will document process measures (e.g., goals; barriers; frequency of self-monitoring) in the tracking system.

Theoretical and Conceptual Framework Guiding the PA and Diet Intervention. Based on Bandura's social cognitive theory[19-21] and the Transtheoretical model,[22] the protocol for individual counseling will follow a step-wise, phased approach to behavior change focusing on key personal, social, and environmental mediators. These constructs have been the basis of previous research on adherence to and determinants of healthy diet and PA; thus, there is empirical support for their efficacy.[23-28] Personal factors include: a) Stage of change, i.e., readiness to adopt behavior changes.[29-31] The intervention approach will be modified according to women's current stage. b) Goal setting. Women will be encouraged to set sequential, realistic, and short-term diet and PA goals. c) Self-efficacy, i.e., confidence in one's ability to adhere to healthy behaviors across situations, previously shown to predict dietary[28] and PA goal achievement.[32-34] The intervention is designed to enhance self-efficacy through successful experiences meeting short-term goals. d) Self-monitoring. Women will be asked to self-monitor their diet and PA to increase awareness of lifestyle behaviors, progress, and barriers to meeting goals. e) Additional factors include positive outcome expectations and the physical benefits of healthy nutrition and PA.[25,28] Social Factors include support for initiating healthy nutrition[35] and PA[25] from family and friends. Women will be encouraged to incorporate their families into behavior change efforts; we will provide tips for seeking diet[36] and PA support[23] e.g., asking a spouse to baby-sit in order to do PA). Environmental factors include cues for diet and PA behaviors. Through counseling contacts, print materials, the intervention will refer women to supportive environments and convenient, cost effective community resources (e.g., home-based exercise for women lacking a safe space for PA; PA classes offering childcare for women

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without spousal support). Barriers related to social and environmental factors will be specifically addressed in the curriculum. Stimulus-Control strategies include teaching women to prompt themselves to engage in healthy behaviors. Problem-solving. This systematic approach includes defining barriers to behavior change and identifying solutions.[37] Relapse prevention strategies include defining differences between "slips" (i.e., a 2-3 day "step back") vs. "relapses" (i.e., abandoning efforts for 3 weeks. Dieticians will help women identify "high risk" situations that can precipitate slips and relapses and problem solve ways to prevent them.

DATA COLLECTION (Table 2)

Data collectors/Research Assistants. Research Assistants are masked to women's condition assignment.

There are four main sources of data used to evaluate this intervention: 1) electronic medical record (EMR) data; 2) patient surveys; 3) study measurements assessed by trained study personnel at 10 and 32-wks of pregnancy, around delivery and at 6- and 12-months postpartum; and, 4) biospecimens collected by trained health professionals (maternal serum at 10 and 32-weeks of pregnancy and cord blood at delivery).

We collect all the measurements shown in Table 2 among women and their infants assigned to each arm. Data will be collected by trained research assistants who are blinded to treatment assignment.

Table 2. Variables measured at study clinic visits

	Pregnancy			Postpartum	
Women characteristics	10 wks	32 wks	Delivery	6 mos	12 mos
Age, Race-ethnicity, literacy	X				
Working and marital status	X				
SES/household/children	X				
Smoking, Alcohol	X				
Medical and weight history	X				
Women Outcomes					
Weight	X	X	X	X	X
Height	X				
Body Fat (subsample)	X	X			
Glucose and insulin	X	X			
Lipids (Chol, triglycerides, LDL, HDL, VLDL)	X	X			
Leptin, Adiponectin,	X	X			
Free fatty acid	X	X			
Diet and Physical activity	X	X		X	X
Covariates					
Depression/Stress/Sleep	X	X		X	X
Lactation and infant feeding				X	X
Stage of change	X	X			
Self-efficacy/Social support	X	X			
Perinatal complications (GDM, PIH, Pre-eclampsia, preterm,)		X	X		
Acceptance of intervention		X*			
Infants Outcomes					
Weight			X	X	X
Flank skinfold thickness and length (subsample)			X		
Cord blood for: Glucose, Insulin, C-peptide, Leptin Adiponectin, Free fatty acid (subsample)			X		
Perinatal complications (macrosomia, low birthweight, LGA, SGA)			X		

* Only among women in the intervention arm

EMR will be used to gather information at the regular clinic and laboratory visits during pregnancy 10- and 32-week pregnancy assessments, at delivery and at 6 months and 12-months postpartum assessments. The EMR data also includes information on pre-gravid weight, smoking, alcohol

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consumption, gestational weight gain, medical history, new pregnancy episodes, perinatal complications.

Survey data will be collected from patients in the intervention group and in the usual care group by a 30-minute self-administered survey and fat, sugary, fruit and veggie screener at around 10- and 32-weeks of pregnancy and at 6-months and 12-months postpartum. Additional information on diet will be collected through administration of a 24-hour diet recall telephone interview at ~12 and 30-weeks of pregnancy. The survey will focus on demographic information, SES, smoking and alcohol use, medical history, pregravid weight, behaviors (diet, physical activity and breastfeeding), depression, stress, sleep, stages of change, self-efficacy and social support, quality of well-being and adverse events.

Study measurements by study staff.

Data collectors/Research Assistants. Research Assistants are masked to women's condition assignment. They will be provided with an 8-week in-depth training and undergo a certification process, in which they will be assessed on each component of the study clinic assessments and standardized protocols. Research Assistants will be trained in the areas related to anthropometry (maternal weight and height, infant weight, length and flank skinfold), basic life safety, bioimpedance spectroscopy for measuring maternal BMI, blood draw facilitation, clinic safety, clinic etiquette, compliance, consent, culturally competent care, diet recall assessment, health connect, physical activity assessment, recruitment, scheduling, survey administration and interviewing, and the overview of the GLOW study. Certification of staff will require shadowing of five baseline assisted clinic visits, three pregnancy follow-up assisted clinic visits, five delivery measurement assisted clinic visits and three 6- and 12-month postpartum assisted clinic visits per study staff at each facility. In addition, we will conduct annual recertifications which will include observation and evaluation of research staff conducting one of each of the baseline clinic visits, pregnancy follow-up clinic visit, delivery measurement visit, and 6 and 12-month postpartum visits. Recruitment recertification will also be completed through a review and assessment of recorded recruitment calls. Recruitment staff will be assessed on communication skills, rapport building and interviewing techniques.

Women's weight and height will be measured at the baseline study clinic visit at 10 weeks' gestation by trained research staff using a standard scale and stadiometer. Women will wear light-weight clothing without shoes, with measurements taken in duplicate to the nearest 0.1 lb. and 0.1 cm, respectively. The average of the two measurements will be used if the difference between them is less than 1.0 lb. or 1.0 cm, respectively; otherwise, a third measurement will be taken. Weight will likewise be measured at study clinic visits conducted at 32 weeks' gestation, delivery, and at 6 and 12 months postpartum. Maternal weight will be measured at both 10- and 32-week pregnancy assessments, within 7 days of delivery and at ~6 and ~12 months postpartum.

Maternal Body Fat Mass. Body fat, using the bioimpedance spectroscopy device, will be measured at around 10- and 30-weeks of pregnancy. Dr. King, a consultant on this application, has shown that bioimpedance spectroscopy (BIS), a multiple frequency bioimpedance analyzer that measures electrical resistance over a broad range of frequencies [rather than at two or three frequencies, as used by bioimpedance analyzers (BIA)], estimates total body water and ECF as accurately as isotope dilution procedures in pregnant women.[38] Thus, we will use BIS to

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measure the changes in TBW during pregnancy. Validated equations for predicting total body fat from the changes in body weight and TBW[39] will be used to estimate body fat changes in our participants. To obtain accurate measurements that generate a normal curve, staff will be required to follow a detailed protocol with careful precision: 1) remove metal jewelry; 2) confirm they are not wearing a cardiac pacemaker, aneurism clip or metallic stents; 3) place electrodes on the participant's left wrist and ankle; 4) clip the leads such that the red and yellow are connected to the wrists and the blue and black are connected to the ankles with the red and black always in the distal position; 5) place the participant's feet so they are spread hip distance apart and move arms are so they are not touching their sides; and, 6) enter previously measured baseline height and current weight into the device.

Maternal Dietary and PA. Diet and physical activity will be assessed at 10- and 32-weeks pregnancy (within 7 days of having completed the baseline and pregnancy follow-up visits). During both pregnancy assessments (10- and 32-weeks of pregnancy), we will conduct three 24-hr dietary recalls over one week (including one week-end day and two week days).[40] Interview days will be randomly selected around each of the data collection points. Trained and certified *Nutrition Assessment* staff from the Fred Hutchinson Cancer Research Center at the University of Washington will conduct recalls over the telephone and the data will be entered directly into a computer using the Minnesota Nutrition Data System for Research (NDSR) software, which is recognized as one of the best nutrient composition databases for research purposes[41-44] and contains a computerized interface[45] to ensure uniformity in interview conduct. The Fred Hutchinson Cancer Research Center will calculate total daily energy and nutrient totals; the mean of three days will be used to estimate daily intake. During both prenatal and postpartum assessments, participants will be asked to complete a fat, sugar, fruit and veggie screener survey developed by Berkeley Analytics/Nutrition Quest. To ascertain levels of physical activity at both prenatal and postpartum assessments, we will use the validated Pregnancy Physical Activity Questionnaire (PPAQ),[46] and the Physical Activity in the Last Month (LCAT)[47] questionnaire which are recommended for use in pregnancy and postpartum. In addition, physical activity levels will be assessed during the prenatal assessments using the ActiGraph GT3X-plus activity monitors, which will be worn on the participant's non-dominant hand for a 7-day period. On-and-off-wear-times as well as special activities not otherwise picked-up by the activity monitor, will be recorded in an activity log (e.g., swimming, yoga, jogging with a stroller). Physical activity summary variables will be constructed from the accelerometer data for women with at least 10-hours of recording time in a 24-hour period for at least 4 days.

Biospecimen samples. Maternal blood will be collected by trained health professionals. At around 10- and 32-weeks of pregnancy, research staff will place the standing research blood draw order, P1.3 for consented participants. Facility phlebotomists will conduct the blood draws in accordance with California State Licensing regulations as well as CLIA (Clinical Laboratory Improvement Amendments)/CMS (Centers for Medicare and Medicaid Services) regulations. Two 6 mL EDTA tubes ("pink top") and one 8.5 mL SST tube ("red/tiger top") will be collected. All blood analyses will be performed at the Northwest Lipid Metabolism and Diabetes Research Laboratories, University of Washington.

Maternal metabolic markers. Fasting blood samples will be collected at around 10-weeks and 32-weeks of pregnancy to measure glucose, insulin, total cholesterol, triglycerides, LDL, HDL, adiponectin and leptin and free fatty acid. Samples will be collected by facility phlebotomists who will conduct the blood draws to obtain two 6 mL EDTA tubes ("pink top") and one 8.5 mL

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SST tube in accordance with California State Licensing regulations as well as CLIA (Clinical Laboratory Improvement Amendments)/CMS (Centers for Medicare and Medicaid Services) regulations. Research Assistant's will observe that the correct tubes are being collected and will note whether the participant is fasting and what time the blood draw occurred
Cord blood will be collected from study participants at delivery. The collection process will be completed as part of the standard cord blood collection at delivery. A study nurse at the Perinatal Center Santa Clara Kaiser location who has MA access to each participant's electronic medical record will add instructions to the participant's problem list for the labor and delivery physician and nursing staff. The admitting physician will place an order for a Miscellaneous Reference Test when the participant is admitted for delivery which will instruct the labor and delivery nurse to collect one EDTA and one SST tube in addition to the cord blood sample collected as a part of standard procedures.

Cord blood metabolic markers. Samples will be obtained to measure infants' glucose, insulin, C-peptide, adiponectin[48,49]and leptin[50,51] and free fatty acid.[52,53] Cord blood is routinely collected at KPNC hospitals. In addition to the standard cord blood collected at delivery, an extra EDTA and SST cord blood sample will be collected by labor and delivery staff for our study purposes. To ensure collection of cord blood, when each participant reaches 30 weeks of pregnancy, a study nurse will add instructions for the admitting physician and nursing staff, to the problem list of each participants' electronic medical record, to alert the admitting physician to place a Miscellaneous Reference Test when the participant is admitted to the hospital. This information will instruct the labor and delivery nurse to collect one EDTA and one SST tube in addition to the cord blood sample collected as a part of standard procedures.

Infant birthweight. Birthweight will be obtained from EMR and defined according to the KPNC race-ethnicity and gestational-age specific birth weight percentiles as SGA (< 10th), AGA (10th to 90th) and LGA (>90th).[54]

Infant Weights and Lengths within 7 days of delivery, 6-months and 12-months. Infant (recumbent) length will be measured by trained study staff within 7 days of delivery and at 6- and 12-months of age. Staff will follow a standard protocol with training guidance from Dr. Patrick Catalano—an expert in obtaining neonatal measurements.[55] Length will be obtained using a Seca infantometer (neonatal length board). For accuracy, measurements will be obtained twice and taken a third time in the event of a difference between the first and second measurement that is greater than 0.5 centimeters. Infant weight will be measured at 6- and 12-months of age. Birthweight will be measured by trained research staff by following a standard protocol that utilizes an annually calibrated Scaletronix infant scale within the maternity ward. For accuracy, measurements will be obtained twice and taken a third time in the event of a difference between the first and second measurement that is greater than 0.45 kilograms.

We will obtain infant weight at 6 and 12 months by calculating the difference between the combined weight of mother and baby from mother's weight alone. Measurements will be taken twice and taken a third time in the event of a difference between the first and second measurement that is greater than 0.5 kilograms. Weight will be obtained using an annually calibrated Scaletronix bariatric scale available within each facility. The WHO child growth standards will determine the weight-for-age, length-for-age, weight-for-length and BMI-for-age percentiles.[56,57]

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Infant percent body fat at birth (for a subsample). Flank skinfold thickness at birth will be measured twice on the left side of the infant's body and averaged. Fat mass at birth will be calculated from birthweight, length, and flank skin fold according to the equation of Catalano et al.[55], which was based on measurements of total body electrical conductivity (TOBEC); percent body fat will be calculated as 100 x fat mass/birthweight**.**

Characteristics that may affect response and/or adherence to the intervention.
We will collect data from participants that might affect response or adherence to the intervention. These include medical history, weight history and lifestyle variables such as sleep,[58] smoking, alcohol and caffeine use; demographics, SES; depression[59] and stress,[60] and stage of change,[30,61] self-efficacy,[20,62,63]and social support[64] for diet and PA. Lactation and infant feeding will be collected.[65-68] More specifically:

Medical History and Lifestyle Variables. Information on reproductive history, medical conditions, medication use, pregnancy weight gain, pregnancy outcomes, breastfeeding, family history of diabetes, cigarette smoking, alcohol and caffeine use, use of illegal drugs will be obtained from the EMR or the surveys. Pre-pregnancy weight will be obtained from the EMR and be self-reported during the recruitment screening call. Weight history information will be collected during the baseline survey.

Demographics and SES. Mother and father's race-ethnicity, education, occupation, income, marital status, number of people in the household and number of members in the household will be assessed at the baseline survey.

Depression. The Patient Health Questionnaire 8 (PHQ-8) will be used to determine the presence and severity of depressive disorders among study participants at both prenatal and postpartum clinic assessments. The PHQ-8 has been previously validated.[59]

Stress. Using Cohen's measure of perceived stress, women's levels of stress will be assessed at the prenatal assessments.[60]

Stages of Change. Using standardized questionnaires, we will assess each woman's current stage of change for decreasing dietary fat[29,30] and increasing physical activity.[31]

Self-efficacy. Self-efficacy is defined as an individual's confidence in his/her ability to successfully perform specific types of health behavior activities (performing specific types of physical activity, reaching healthy dietary goals, etc.) during a given time period.[20,62,69] We will use the self-efficacy for physical activity scale, which assesses a woman's confidence for being able to perform different types of physical activity and overcome specific barriers. Self-efficacy for goal levels of fat intake and eating less fat will be measured by adapting methods similar to those used by others.[63,70,71]

Social Support. Social support measures related specifically to physical activity are strong predictors of exercise adherence.[72] To assess social support, six items will be selected from the Family/Friend Support for Exercise Habits Scales.[70] Similar measures for social support for changes in diet will also be used measures.[64,69,70,73]

Lactation and infant feeding. Information about breastfeeding and infant feeding will be collected at the postpartum assessments using standardized interview-administered questions.[65-68]

Measures related to Delivery and Receipt of the Intervention

Process Measures. We will collect process measures related to the intervention such as attendance, length of time needed to deliver the intervention, and number of missed contacts.

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Acceptability. The acceptability of the intervention will be measured by women's recall of their participation in intervention events.
Self-monitoring. We will measure self-monitoring during each in-person and telephone session focusing on self-monitoring of weight, calorie and diet as well as activity.

Data Safety and Monitoring Board (DSMB). We propose a DSMB to enhance the integrity of study procedures and data quality. We will conduct annual DSMB meetings that will involve board members as well as research scientists, programmers and project coordinators. The meetings will involve a one-hour investigator-led presentation, corresponding to the contents outlined in a previously sent report two-weeks in advance of the meeting. The contents of the presentation will include an overview of the study, the study aims and outcomes, study flow (e.g., recruitment and retention), intervention (e.g., retention, session administration, LSC fidelity, etc.), preliminary results and possible adverse events. Following the one-hour presentation, a closed session discussion between the board members will occur to provide them an opportunity to further discuss the study and issues presented and whether any should result in a pause to the study procedures, protocol changes, etc. A designated note-taker will be asked to take thorough minutes during the presentation and the closed session discussion after which s/he will disseminate them to all attendees of the meeting. The DSMB will receive annual reports and may request additional reports due to unforeseen problems. The occurrence of serious adverse events (AE) is not a large concern, but we will collect data on AEs from the EMR and study questionnaires.
The GLOW DSMB includes: Dennis M. Black, PhD, biostatisticians at University of California, San Francisco, who serves as the chair of the DSMB; Cheryl Albright, PhD, clinical psychologist and behavioral scientist at the University of Hawaii at Manoa; and Naomi Stotland, MD, obstetrician and researchers at the University of California, San Francisco.

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Summary of Changes to the GLOW Protocol

OUTCOMES

Primary outcomes. In the original protocol, the primary outcomes included total gestational weight gain that now is among the secondary outcomes. The reason is that we realized possible reduction in sample size due to pregnancy losses, given the early stage of pregnancy at which women were enrolled. Therefore, rates of GWG per week was the primary outcomes, which allowed a complete estimation among nearly all women, regardless of possible pregnancy losses. We also no longer had rate of GWG per week between 10 and 32 weeks of gestation as a primary outcome, given the lower clinical significance of this outcome.

Secondary outcomes. In the original protocol, one of the secondary outcomes was changes in body fat between 10 weeks and 32 weeks gestation. However, in the final protocol, we no longer have body fat as a secondary outcome. The reason was that we received a substantial budget cut and therefore we were not able to assess body fat in all medical centers we recruited from.

RECRUITMENT, ELIGIBILITY & EXCLUSION CRITERA

- **Eligibility Criteria:**
  - **BMI.** In the original protocol, we did not have un upper limit for pre-pregnancy BMI. Later we restrict eligibility to women who did not have a BMI greater than 40.0 kg/m^2. Restricting BMI eligibility to no greater than 40.0 kg/m^2 was included because there are higher medical risks associated with the Class 3 obesity BMI category.
- **Exclusion Criteria (EMR Review and Recruitment call):**
  - In the original protocol, we aimed to exclude any woman with multiple gestations, pre-pregnancy weight within 6 months of prior pregnancy, pre-pregnancy diabetes, hypertension, history of miscarriage or stillbirth, serious gastrointestinal diseases or bariatric surgery, chronic hepatitis, renal insufficiency, or psychiatric and eating disorders.
    - In the final protocol exclusion criteria were added
      - medical conditions that may affect weight such as 1) fertility-assisted pregnancy; 2) thyroid disease diagnosed in the last 30 days; 3) current corticosteroid use (oral or injected);
      - medical/social conditions that are associated with ones capacity to physically or psychologically participate in the *Getting in Balance* intervention: 1) history of or current psychiatric conditions (serious mental health disorders including depression, post-traumatic stress disorders, bipolar disorders, etc.); 2) drug or alcohol; 3) medical conditions that would prevent participation in intervention arm of the study (i.e. uncontrolled exercise induced asthma, provider recommendation to avoid exercise); and, 4) conditions that lead to diet changes (i.e., renal insufficiency); 5) history of cardiovascular disease; 6) history of lung disease such as emphysema and COPD or history of cancer.
      - situations that would interfere with participants full participation in the

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study: 1) plans to move out of the geographic area in the next two years; 2) extensive travel plans during pregnancy; 3) plans to get pregnant in the year after delivery; 4) no access to reliable transportation; 5) no access to consistent telephone; 6) are non-English speaking; and currently breastfeeding.

- **Exclusion Criteria (Recruitment call):** During the recruitment call we added as exclusion criteria women whose self-reported weight was ± 5 pounds of what was recorded in their electronic medical record. We required this agreement to facilitate negotiation between dieticians and participants assigned to the intervention condition in setting the total amount of weight to be gained during pregnancy, since prepregnancy weight from EMR was used to calculated prepregnancy BMI and to set weight goal.
- **Exclusion Criteria (Baseline clinic visit):** An additional tier of exclusion criteria was included to assess participants commitment level to the study. Women who completed the baseline clinic visit, which includes the collection of anthropometric and survey data, were asked to complete a diet and physical activity assessment within two weeks of the visit. They were asked to complete three 24-hour diet recalls (by telephone) and to wear an accelerometer for 10-hours for at least 4 days in addition to completing logs for physical activity. Completion of these assessments were added as a further tier of screening to assess participants' level of commitment to the study in addition to providing baseline data on diet and physical activity. If participants completed less than four 10-hour days of accelerometer data, they were not considered eligible for randomization.
- **Orientation session:** Mid-way through the trial, we implemented an orientation session protocol between the recruitment call and baseline visit to better calibrate expectations and improve retention in the pregnancy intervention. Women participated in an orientation session via a conference call, in small groups or individually, with written materials emailed or mailed in advance. A co-investigator or project manager facilitated the discussion, e.g., eliciting pros and cons of random assignment, discussing commitments to clinic visits and intervention activities, and whether women could make time to participate. After completion of the orientation session, participants made an informed decision to participate and scheduled their baseline clinic assessment.

RETENTION STRATEGIES

- **Retention strategies:** Due to provider time-burden, we were unable to use provider letters to encourage participation as a retention strategy. To retain participants for the delivery assessment, in place of the infant cards, research staff sent delivery assessment reminder cards two-weeks prior to the participant's estimated delivery date. The delivery measurement card included information regarding the participant's preferred method of being contacted after delivery (text, email, phone-call), and what to expect during the 20-minute assessment. In addition to the $50 Target gift card given at delivery, the mothers also received a congratulatory magnet with the GLOW logo and hotline number. Both pregnancy and postpartum newsletters and nondenominational holiday cards were used as additional retention strategies throughout the duration of the study. In addition, participants were asked at the end of each survey whether their contact information had changed, and, in the event we could not reach them for their next assessment, we requested friend and/or family contact information.
- **Incentives:** In the original protocol, we aimed to give participants $30 for the completion of each clinic assessment. In the final protocol, $50 Target gift cards were given to each

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participant for the completion of each of the 5 clinic visits, for a total of $250 in gift cards. The denomination was increased by $20 per visit due to the increased time burden of each assessment.

INTERVENTION

Overview of Lifestyle Intervention

- Stress management was added as a 4th goal of the *Getting in Balance* lifestyle program, in addition to weight and nutrition management and increasing/maintaining physical activity. The stress management goal was included to help participants develop skills to reduce and manage stress, with a particular focus on managing stress to support healthy lifestyle choices (e.g., healthy diet and activity behaviors).
- In the final protocol, participants were offered multiple options for tracking diet (calories and fat intake), weight and physical activity rather than the single paper tracking option proposed in the original protocol. The options included:
  1) providing participants with a fat counter dictionary and 12 "Keeping Track" booklets with self-addressed stamped envelopes to mail booklets to lifestyle coaches on a weekly basis;
  2) giving participants access to the study-specific Nutrihand website for tracking their diet and physical activity; however, given its poor user-friendly interface, and it not being designed for diet and physical activity tracking via a phone it was not highly utilized; and,
  3) allowing participants to use diet and physical activity tracking smartphone applications (e.g., MyFitness Pal).
- To facilitate self-monitoring of weight (weight-tracking), participants were given a scale in addition to the personalized graphs of gestational weight gain trajectories. Participants were also given the option to track their weight using MyFitness Pal (see above).
- In the original protocol, we aimed to develop a website that aligned with the structure of the in-person and telephone sessions that also provided access to all print materials and secure messaging; however, it was not developed due to budgetary constraints.
- The intervention was not offered in Spanish as initially intended due to budgetary constraints and due to the revised eligibility criteria which excluded participants who were non-English speakers.

Early Prenatal Phase I

- Due to the number of eligibility screening activities required for participation, we extended the timeframe for starting the program from 12 weeks gestational age to no later than 15 weeks gestational age. This still allowed participants to complete the early prenatal phase of the intervention by around 30 weeks of pregnancy.
- **Targets [gestational weight gain (GWG)]**
  - Recommendations for total gestational weight gain were revised to reflect the lower bound value set by the Institute of Medicine (IOM) for total GWG as the upper limit for weight gain during pregnancy: 4.9 kg (15 lbs.) for overweight women and 6.8 kg (11 lbs.) for obese women in place of the midpoint for total GWG as the upper limit: 7-9 kg for overweight women and 5-7kg for obese women.

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- In the original protocol, we used the prepregnancy BMI-specific charts developed by the IOM for recommended rates of GWG by week of pregnancy during the second and third trimesters, with means (ranges) as follows: 0.28 (0.23-0.33) kg/week for overweight and 0.22 (0.17-0.27) kg/week for obese women. In the final protocol, prepregnancy BMI-specific charts were modified to reflect the lower bound value of weight gain recommended by the IOM and women were asked not to exceed gaining more than 0.5 pound per week.
- In the original protocol there were no weight gain guidelines for women who had already exceeded weight gain recommendations. In the final protocol, women who had exceeded the recommendations were advised to maintain their current weight. All women were encouraged to discuss questions with their providers.

- **Diet**
  - The original protocol recommended a calorie goal range from 15 to 20 Kcal/kg current body weight, according to physical activity levels and weeks of pregnancy. In the final protocol, the initial calorie goal was based on the participants overall weight gain progress as well as weight gain and calorie intake between sessions 1 and 2. The initial calorie goal was determined by interventionists, using the *Session 2: Initial Calorie Goal Setting* schema outlined below. Participant weight gain continued to be evaluated at subsequent sessions (3-17) and calorie goal adjustments were made based on between-session weight gain and the previous week's calorie goal. Subsequent calorie goals were determined by interventionists, using the *Sessions 3-17: Calorie Goal Adjustments* schema outlined on the next page.

Session 2: Initial Calorie Goal Setting	
Scenario…	***Interventionist instructions…***
If the participant HAS tracked her diet for more than one day or more in the last week (7 days), and HAS NOT exceeded 0.5 lbs weight gain…	provide a calorie goal based on last week's calorie information (continue what she has been doing).
If the participant HAS tracked her diet for more than one day or more in the last week (7 days), and HAS exceeded 0.5 lbs weight gain…	recommend a 200 calorie decrease for the following week; however, don't recommend a calorie goal below 1200 calories.
If the participant HAS NOT tracked her diet in the last week and HAS NOT exceeded 0.5 lbs weight gain…	the calorie goal should be established through the *GIB 24-hour Diet Recall Procedure*. The re-established calorie goal is based on the total calories calculated from the diet recall.
If the participant HAS NOT tracked her diet in the last week and HAS exceeded 0.5 lbs weight gain…	The calorie goal should be reestablished through the *GIB 24-hour Diet Recall Procedure.* The re-established calorie goal is based on the total calories calculated from the diet recall minus 200 calories; however, adjustments will be made if reducing calories by 200 results in the new calorie goal being below 1200 calories per day. (note: the calorie goal should not be below 1200)

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Sessions 3-17: Calorie Goal Adjustments	
Scenario…	***Interventionist instructions…***
If the participant HAS tracked her diet for one day or more in the last week (7 days), is meeting her calorie goal and HAS NOT exceeded 0.5 lbs weight gain…	provide a calorie goal based on last week's calorie information (continue what she has been doing).
If the participant HAS tracked her diet for one day or more in the last week (7 days), is meeting her calorie goal and HAS exceeded 0.5 lbs weight gain…	recommend a 200 calorie decrease for the following week; however, don't recommend a calorie goal below 1200 calories.
If the participant HAS tracked her diet for one day or more in the last week (7 days), is exceeding her calorie goal and HAS exceeded 0.5 lbs weight gain…	don't adjust the calorie goal. Instead, utilize motivational interviewing techniques to strategize on how to meet the currently set calorie goal.
If the participant HAS tracked her diet for one day or more in the last week (7 days), is exceeding her calorie goal and HAS NOT exceeded 0.5 lbs weight gain…	don't adjust the calorie goal. Instead, re-evaluate weight gain at the subsequent session.
If the participant HAS NOT tracked her diet in the last week and HAS NOT exceeded 0.5 lbs weight gain…	the calorie goal should be established through the *GIB 24-hour Diet Recall Procedure*. The re-established calorie goal is based on the total calories calculated from the diet recall.
If the participant HAS NOT tracked her diet in the last week and HAS exceeded 0.5 lbs weight gain…	the calorie goal should be reestablished through the *GIB 24-hour Diet Recall Procedure.* The re-established calorie goal is based on the total calories calculated from the diet recall minus 200 calories; however, adjustments will be made if reducing calories by 200 results in the new calorie goal being below 1200 calories per day. (note: the calorie goal should not be below 1200)

Late Prenatal (Phase II, maintenance)

- In the original protocol, during *late prenatal phase,* we planned to mail 2-3 biweekly personalized brochures via mail or email (based on preference), containing the following: 1) suggestions for maintaining or increasing physical activity and decreasing fat intake as assessed at the end of Phase I; 2) encouragement to self-monitor weight, diet and physical activity at least 1 week each month; 3) referrals to the original study materials; and 4) culturally-appropriate recipes. In the final protocol, in place of the mail-only intervention, four 15-minute bi-weekly phone-based sessions with the lifestyle coach were scheduled to assist participants in continuing to monitor their weight towards the end of their pregnancy. The Lifestyle coach and participant used the *Use Options Tool* available in the guidebook to collaboratively decide on which topics from the 13-core session to repeat

Training

- **Interventionists.** In the original protocol, we aimed for Interventionists to receive 16-hours of standardized training in social cognitive strategy and MI for diet and PA behavior change and have them attend 1 half-day training session per year. In the final protocol, interventionist received 6-weeks of study-specific training in addition to the 16-hours of MI training covering areas, including overview of the GLOW study, overview of the Getting in Balance Program, interviewing techniques, compliance and handling of private health information, team communication, clinic etiquette and general clinic safety,

CONFIDENTIAL

ACCESS database tracking system, data entry and scheduling. Intervention-specific trainings covered protocols related to each program goal (weight, improving nutrition, increasing physical activity and managing stress), conducting sessions (sequence and content, scheduling, session reminders and call attempts), key principles underlying the intervention, retention, quality assurance, intervention fidelity and intervention evaluation.

Adherence to the Intervention Protocol and Monitoring of the Intervention Process
Intervention delivery. In the original protocol, the project coordinator aimed to review a random 10% sample of recorded intervention sessions. In the final protocol, the project coordinator reviewed a random 20% sample 5-sessions representative of the program goals and key intervention components across the core 13-session curriculum:

- Session 1: Welcome to Getting in Balance
- Session 2: Getting Started with Healthy Eating
- Session 3: Getting Started with Physical Activity
- Session 9: Handle Challenging Feelings and Triggers
- Session 13: Staying Motivated

DATA COLLECTION

Overview of data collection

- **Survey.** Per the guidance of the Data Safety Monitoring Board members, we added questions to the 30-week survey assessment related to adverse events. Questions included, *Since your last GLOW visit, did you…1) have pain or cramping in your leg, knee or foot?; 2) pull or strain a muscle, tendon or ligament?*; and, *3) break any bones?* For patients in the intervention group, we also collected data on acceptance of the intervention at the end of the intervention period.
- **Maternal Dietary.** In the original protocol, 24-hr dietary recalls were to be performed at 10- and 32-weeks of pregnancy and at 12-months postpartum by study staff, trained in conducting recalls using the Minnesota Nutrition Data System for Research (NDSR). In the final protocol, the dietary recall interviews were only performed during the pregnancy visits and were conducted by external staff at the University of Washington Fred Hutchinson Cancer Research Center, who have training in NDSR. In the original protocol it was also proposed that participants complete a food frequency questionnaire (FFQ) at 10- and 32-weeks of pregnancy and at 12-months postpartum. Instead of the FFQ, a shorter self-administered fat sugar, fruit and veggie screener survey was completed by participants at both prenatal and postpartum assessments. The standardized screener was developed by Berkeley Analytics/Nutrition Quest.
- **Maternal PA.** In the original protocol, physical activity levels were ascertained using the Pregnancy Physical Activity Questionnaire (PPAQ) and the ActiGraph GT3X-plus activity monitors at both prenatal and postpartum assessments. In the final protocol, physical activity levels were ascertained using both the PPAQ and the Physical Activity in the Last Month (LCAT)[47] survey questions at both prenatal and postpartum assessments. Physical activity levels were also assessed using the ActiGraph GT3X-plus activity monitors, but only during the prenatal visits. Participants were also asked to record their on- and off-activity-monitor-wear-times as well as special activities not otherwise picked-up by the physical activity monitor (e.g., swimming, yoga, jogging with a stroller).
- **Maternal Body Fat Mass.** In the original protocol, we planned to assess maternal body fat using the bioimpedance spectroscopy device at both prenatal and postpartum

CONFIDENTIAL

assessments; however, given the length of the appointments and the high cost of the electrodes needed for the measurements, we only measured maternal body fat during the pregnancy visits and only in a subsample.

- **Infant Weight and Length.** In the original protocol, we planned to assess infant weight and length at 6- and 12-months postpartum in order to calculate BMI to determine child growth standards according to the WHO weight-for-age, length-for-age, weight-for-length and BMI-for-age percentiles. In the final protocol, length was also taken within 7-days of delivery in order to calculate infant percent body fat at birth, utilizing the equation of Catalano et al.

- **Maternal pregnancy fasting blood samples.** In the original protocol, we planned to have Northwest Lipid Metabolism and Diabetes Research Laboratories measure glucose, insulin, total cholesterol, triglycerides, LDL, HDL, adiponectin and leptin in samples collected from pregnant women around 10- and 30-weeks of pregnancy. In the final protocol, free fatty acid was included as an additional measure.
- **Cord blood samples.** In the original protocol we planned to have study staff obtain cord blood samples and bring them to the lab for processing within 30 minutes of delivery. Given the constraints of having hourly research staff available for participant deliveries at any hour of the day and night and over the weekend, we had to develop an alternate solution for obtaining participant cord blood. A complex protocol for obtaining an extra sample of cord blood at delivery was developed as a part of the final protocol and was implemented with buy-in from departmental, provider and clinical laboratory staff. The collection process was completed as part of the standard cord blood collection at delivery. At 30-weeks gestational age, a study nurse added instructions for the admitting physician and nursing staff, to the problem list of each participants' electronic medical record. The admitting physician was directed to place an order for a Miscellaneous Reference Test when the participant was admitted for delivery, instructing the labor and delivery nurse to collect one EDTA and one SST tube in addition to the cord blood sample collected as a part of standard procedures. Additionally, in the original protocol, we planned to have Northwest Lipid Metabolism and Diabetes Research Laboratories measure infants' glucose, insulin, C-peptide, adiponectin and leptin. In the final protocol, free fatty acid was included as an additional measure.
- **Infant percent body fat at birth.** Per guidance from Dr Catalano, during an in-person three-day training at Case Western University, it was suggested that flank skinfold be measured twice rather than in triplicate. A third measurement was only taken in the event of a discrepancy between the first two measurements of more than 0.5 millimeters.

Training

Data Collectors/Research Assistants. In the final protocol, Research Assistants were provided with an 8-week in-depth training and undergo a certification process, in which they will be assessed on each component of the study and standardized protocols. Research Assistants were trained in the areas related to *anthropometry (maternal weight and height, infant weight, length and flank skinfold), basic life safety, bioimpedance spectroscopy for measuring maternal BMI, blood draw facilitation, clinic safety, clinic etiquette, compliance, consent, culturally competent care, diet recall assessment, health connect, physical activity assessment, recruitment, scheduling, survey administration* and *interviewing*, and *overview of the GLOW study*. Certification of staff required that the Project Manager shadow five baseline assisted clinic visits, three pregnancy follow-up assisted clinic visits, five delivery measurement assisted

CONFIDENTIAL

clinic visits and three 6- and 12-month postpartum assisted clinic visits per study staff at each facility. In addition, we conducted annual recertifications which included observation and evaluation of research staff conducting one of each of the baseline clinic visits, pregnancy follow-up clinic visit, delivery measurement visit, and 6 and 12-month postpartum visits. Recruitment recertification will also be completed through a review and assessment of recorded recruitment call. Recruitment staff will be assessed on communication skills, rapport building and interviewing techniques.

Measures related to Delivery and Receipt of the Intervention

Self-monitoring. In the original protocol, we aimed to measure self-monitoring by the number of self-monitoring booklets completed. In the final protocol, self-monitoring was assessed during each in-person and telephone session focusing on self-monitoring of weight, calorie and diet as well as activity.

Data Safety and Monitoring Board

In the original protocol we proposed a Data Safety and Monitoring Board to enhance the integrity of study procedures and data quality and that they would receive quarterly reports to assess the occurrence of serious adverse events. In the final protocol, the DSMB members received an annual report and were asked to attend an annual two-hour conference call during which a presentation outlining study status updates and adverse events were discussed.

CONFIDENTIAL

SECTION 2

CONFIDENTIAL

STATISTICAL ANALYSIS PLAN

STATISTICAL ANALYSIS PLAN

Randomization and representation. We will first produce descriptive statistics, overall (N=400) and separately by arm, for the purpose of assessment of the baseline comparability of the two arms. Women who are lost to active follow-up will be compared with those who remain in terms of baseline characteristics.

All analyses will be by intent-to-treat and will be adjusted for the variables used in the adaptive randomization procedure (age, pre-pregnancy BMI category, race/ethnicity and medical center).[74] The impact of including baseline confounders in our estimation of treatment effect will be assessed, with focus on variables with chance imbalance in distributions by treatment group.

Primary outcome weekly rates of GWG. The proportion of women exceeding the IOM guidelines for weekly rate of GWG will be compared via modified Poisson regression[75] providing point and interval estimates of relative risk. Multiple linear regression will be used to provide point and interval estimates of the overall difference between usual care and intervention conditions in mean weekly rate of GWG.

Subgroup analyses of GWG with interaction test for heterogeneity in condition effect will be performed for pre-pregnancy BMI (overweight, obese).

Secondary GWG outcomes. The proportion of women exceeding the IOM guidelines for total GWG and the proportion of women meeting the trial goals will be compared via Poisson regression[75] providing point and interval estimates of relative risk.
Multiple linear regression will be used to provide point and interval estimates of the overall difference between usual care and intervention conditions in mean total GWG and rate of GWG per week between study clinic visits.

Secondary outcomes diet, physical activity and metabolic markers. Multiple linear regression will be used to provide point and interval estimates of the overall difference between usual care and intervention conditions in means. For categorical variables, Poisson regression[75] will be used to compare conditions providing point and interval estimates of relative risk.

Analysis related to cord blood levels of metabolic markers, birthweight and perinatal outcomes. For all categorical variable we will use Poisson regression[75] to compare conditions providing point and interval estimates of relative risk. Multiple linear regression will be used to provide point and interval estimates of the overall difference between usual care and intervention conditions in mean.

CONFIDENTIAL

Mediation analyses. Mediation analyses[76] will be conducted to examine the proportion of the intervention's effect on secondary and exploratory outcomes that is mediated by GWG, when appropriate.

Analyses related to 6 moth and 12 months postpartum outcomes. Analyses of postpartum weight in mothers, and on anthropometric measurements in infants will parallel that described above for analyses of maternal factors changes during pregnancy, utilizing repeated measures at 6 and 12 months.

Missing data. Inferences based on the mixed effects models in the presence of incomplete data due to missed exams and dropout are valid with an assumption that the missing data mechanism depends only on observed outcomes and covariates (missing at random).[77,78] However, we will conduct sensitivity analyses implementing multiple imputation techniques using multivariate sequential regression.[79] We note that if data is not missing at random (mechanism depends on unobserved outcomes), regression estimates are biased (with or without imputation), but the bias may be very small.[77,78] Noting that we will have weight measures on those who drop out of the study via the EMR, we will have the opportunity to examine the MAR assumption.[77,80,81]

Statistical Power. This study will randomize 400 women during pregnancy, with 200 in the lifestyle intervention arm and 200 in the usual medical care. Our target sample size is 400 participants, with 200 per condition, which was estimated to provide a maximum (protective effect assumed) detectable relative risk (intervention vs. usual care) of exceeding the IOM guidelines for weekly rate of GWG of 0.75 (power=.80, α=.05, two-sided test; expected proportion in the usual care condition = 59%, given preliminary data). This sample size provides 80% statistical power to detect a between-condition difference in mean weekly rate of GWG of at least .053 kg/week, assuming 10% attrition (α=.05, two-sided test; expected standard deviation = 0.18 kg/week given preliminary data).

CONFIDENTIAL

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